

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

BAVARIAN NORDIC A/S,)
Plaintiff,)
v.) C.A. No. 05-614 (SLR)
ACAMBIS INC. and)
ACAMBIS PLC,)
Defendants.)

)

**REPLY BRIEF IN SUPPORT OF DEFENDANTS' MOTION FOR
LEAVE TO FILE AMENDED ANSWER AND COUNTERCLAIMS**

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INTRODUCTION

Pursuant to Fed. R. Civ. P. 15(a) and (d), defendants Acambis Inc. and Acambis plc (“Acambis”) have moved for leave to amend their Answer to add additional counterclaims (D.I. 35). Plaintiff Bavarian Nordic A/S (“BN”) opposes the motion on the grounds of undue delay and prejudice, and that Acambis’ proposed counterclaims are futile.

There is no undue delay or prejudice here. Acambis filed its motion within the stipulated time period for such motions, and on the same day that BN itself filed a motion to amend the Complaint. Moreover, BN cannot point to any specific prejudice that it will suffer as a result of Acambis’ proposed counterclaims beyond some speculative additional litigation costs, which are not a proper basis for denying a motion to amend. Finally, BN’s arguments about the futility of Acambis’ counterclaims are not supported by the relevant law. This Court does not lack jurisdiction over Acambis’ declaratory judgment counterclaims, and Acambis has alleged the requisite elements and factual basis to support its antitrust and other counterclaims. Acambis’ motion to amend should be granted.

ARGUMENT

I. There Is No Undue Delay, And Bavarian Nordic Will Not Be Prejudiced By Acambis’ Proposed Amendments.

Fed. R. Civ. P. 15(a) provides that leave to amend “shall be freely given when justice so requires,” and the U.S. Supreme Court has made clear that “this mandate is to be heeded.” *Foman v. Davis*, 371 U.S. 178, 182 (1962). “If the underlying facts or circumstances relied upon by a plaintiff may be a proper subject of relief, he ought to be afforded an opportunity to test his claim on the merits.” *Id.*

BN opposes Acambis' motion to amend on the grounds that "[t]he delay in bringing these claims is unfairly prejudicial to [BN] and, if they are added, would result in the schedule of this case being significantly extended" (D.I. 42 at 2). Acambis' motion was filed, however, within the time allowed for amendments under the Court's Scheduling Order. Indeed, the parties stipulated, and the Court ordered, that "the date by which the parties may file motions to join other parties or amend the pleadings is extended to and including May 22, 2006" (D.I. 34). Acambis filed its motion on May 22, 2006.

That same day, BN also filed a motion to amend the Complaint to add Professor Anton Mayr as a co-plaintiff (D.I. 38). In support of its motion, BN acknowledged that "[t]he parties have stipulated that, subject to the approval of this Court, the deadline for motions to amend the pleadings and add parties is May 22, 2006" (*id.* at 1). Both parties were permitted to move to amend the pleadings or join additional parties by May 22, 2006 (and both parties did).

In any event, if BN's motion to amend the Complaint is granted, BN's opposition to Acambis' motion to amend is moot. Once BN has filed an Amended Complaint, Acambis is permitted to answer that amended pleading and assert any and all counterclaims -- without leave of Court -- as if Acambis were answering the original Complaint for the first time:

It has long been the rule in this district that in answering an amended complaint the defendant is free to answer not simply the amendments, but the new complaint, as if answering an original complaint. *Joseph Bancroft & Sons Co. v. M. Lowenstein & Sons, Inc.*, 50 F.R.D. 415, 419 (D. Del. 1970) ("Rule 15(a) . . . does not direct a response to the 'amendment,' as it might have, but to the 'amended pleading.'"). Nothing in the rules prevents the defendant from including counterclaims in its answer.

Standard Chlorine of Delaware, Inc. v. Sinibaldi, C.A. 91-188-SLR, 1995 WL 562285, at *2 (D. Del. 1995) (emphasis added); *see also E.I. du Pont de Nemours & Co. v. Millennium Chemicals, Inc.*, C.A. 97-237-SLR, 1999 WL 615164, at *4 (D. Del. 1999) ("Plaintiff . . . offers

no compelling justification for departing from the well established rule that a defendant may include counterclaims in its answer to an amended complaint.”).

Moreover, “[w]ell-established precedent in the Third Circuit dictates that delay, in and of itself, is an insufficient basis for denial of a motion to amend.” *Proctor & Gamble Co. v. Nabisco Brands, Inc.*, 125 F.R.D. 405, 408 (D. Del. 1987). To justify a denial of a motion to amend or supplement, the delay must be “undue.” *See Adams v. Gould Inc.*, 739 F.2d 858, 868 (3d Cir. 1984). There has been no undue delay here. Acambis promptly moved to amend after learning the facts and circumstances of BN’s activity, including its fraudulent conduct, which was uncovered in the parallel ITC action.¹

In discovery in the ITC action and at the ITC trial, which ended on May 15, 2006, just one week before Acambis filed its proposed counterclaims here, Acambis learned and verified important facts that form the basis for its counterclaims here, including: (1) the true origin and history of the strain claimed in BN’s patents; (2) the true role of the named inventors on the patents; (3) the true facts underlying the single experiment that is the basis for the patents in suit; and (4) the facts underlying BN’s claim to a “property” right in the virus underlying MVA3000. As to each of these facts, BN knowingly made false representations to the patent office or in its pleadings.

Once it discovered the necessary factual basis, Acambis promptly sought to add additional counterclaims based on information uncovered during discovery. *See Affinion Net Patents, Inc. v. Maritz, Inc.*, C.A. 04-360-JJF, slip op. at 3-5 (D. Del. June 8, 2006) (rejecting argument that plaintiff “exercised undue delay in requesting leave to amend its Complaint,

¹ BN also seeks to add additional facts that it learned during the ITC action in its motion to amend: “Bavarian Nordic has also made amendments to provide additional information discovered during the pendency of the ITC action . . .” (D.I. 38 at 3).

because it waited until the evening before the deadline for filing expert reports, after months of discovery,” where plaintiff needed to take discovery to confirm the basis for its motion to amend) (Ex. A).²

BN also argues that Acambis’ motion to amend should be denied because the proposed counterclaims are “wholly unrelated to the original action” (D.I. 42 at 5). That is not correct. All of BN’s claims and Acambis’ proposed counterclaims arise out of claims to MVA strains. Whether under the rubric of trade secrets, conversion, patents or antitrust, the issue is whether BN has the right to exclude Acambis from the MVA field. That issue has always been part of this case. In fact, as Acambis notes in its proposed counterclaims, BN references the patents at issue in its own Complaint, and just a few paragraphs later, asserts that Acambis has made false representations regarding its “freedom to operate within the field of MVA-based smallpox vaccines” (D.I. 35, Ex. A, ¶ 49).

Finally, BN argues that it will suffer undue prejudice as a result of Acambis’ motion to amend (D.I. 42 at 7-8). BN must prove that actual prejudice will result if Acambis is granted leave to amend. *See Pegasus Dev. Corp. v. DirecTV, Inc.*, C.A. No. 00-1020-GMS, 2002 WL 598457, at *2 (D. Del. 2002). BN cannot merely claim prejudice, but must show that it has been unfairly disadvantaged or deprived of the opportunity to present facts or evidence that

² BN suggests that Acambis’ earlier motion to stay this action and Acambis’ proposed counterclaims are part of a strategy “designed to delay resolution of Bavarian Nordic’s claims” (D.I. 42 at 7). That is simply not true. The motion for stay was filed in October 2005 on the basis that BN was pursuing identical misappropriation of trade secrets and tortious conversion claims before this Court and the ITC. In April 2006, the ITC Administrative Law Judge summarily dismissed the trade secrets and tortious conversion claims from the ITC proceeding. Those rulings became final on May 9, 2006, and Acambis has since withdrawn its motion to stay (D.I. 43). The proposed counterclaims, on the other hand, are brought on the basis of information learned and verified during the course of the ITC proceeding. As BN acknowledges, the ITC trial concluded on May 15, just one week prior to the filing of Acambis’ proposed counterclaims (D.I. 42 at 1).

could have been presented if the amendments had been made earlier. *Bechtel v. Robinson*, 886 F.2d 644, 652 (3d Cir. 1989).

BN cannot demonstrate any prejudice here. This litigation has not progressed far enough that there could be any prejudice resulting from Acambis' new counterclaims. Moreover, most or all of the necessary discovery has already been taken in the ITC action, and the parties have agreed that those materials may be used in this case. BN does not identify any specific discovery in response to Acambis' proposed counterclaims that BN will not be able to complete during the time allotted, and it is not clear what additional discovery will be necessary. For example, the ITC case involves BN's claims under the same two patents at issue in Acambis' declaratory judgment and antitrust counterclaims. In that case, hundreds of thousands of documents have been exchanged, dozens of depositions taken, and a full six-day evidentiary hearing on the merits concluded several weeks ago. On the antitrust claims, BN concedes that the relevant market has already been defined -- the only relevant sales are those to the U.S. Government through the RFP process (*see* D.I. 42 at 8). In any event, to the extent additional discovery will be necessary (as it will be for BN's proposed amendment to add Professor Mayr as a plaintiff), the schedule can be modified to accommodate those needs.³

Undue prejudice does not result from delay in the movement of a case or from the need to incur additional legal fees. *See Pegasus*, 2002 WL 598457, at *2. As a result, the need for additional discovery does not generally cause the type of undue prejudice that serves as a basis for denying a motion to amend. *See CenterForce Tech., Inc. v. Austin Logistics Inc.*, C.A.

³ BN suggests in its reply in support of its motion for leave to amend to add Professor Mayr as a plaintiff that Acambis should have "moved to compel" materials from Professor Mayer in the ITC proceeding (D.I. 44 at 2). But Professor Mayr was not a party to the ITC proceeding nor did the ITC have jurisdiction over him as he is a resident of Germany.

No. 99-243-MMS, 2000 WL 652943, at *6 (D. Del. 2000); *see also Jenn-Air Prods. Co. v. Penn Ventilator, Inc.*, 283 F. Supp. 591, 594 (E.D. Pa. 1968) (“[P]rejudice ordinarily is not considered to have occurred unless the motion is made during or after the actual trial.”).⁴

Acambis’ motion to amend should be granted. There has been no undue delay, and BN will not suffer any undue prejudice as a result of Acambis’ motion to amend.

II. Acambis’ Amended Counterclaims Are Not Futile.

BN also argues that Acambis’ proposed counterclaims are futile because this Court lacks jurisdiction over Acambis’ declaratory judgment counterclaims, and because Acambis’ antitrust counterclaims fail to allege “antitrust injury” or a “dangerous probability of success.” Those arguments are flawed.

A. The Court Has Jurisdiction Over Acambis’ Declaratory Judgment Counterclaims.

BN argues that Acambis’ declaratory judgment counterclaims concerning the validity and enforceability of BN’s patents are futile because the Court lacks jurisdiction. According to BN, the Court lacks jurisdiction because Acambis is a government contractor, and pursuant to 28 U.S.C. § 1498, a patentee’s only remedy for patent infringement by a government contractor is an action in the Court of Federal Claims against the U.S. Government (D.I. 42 at 8-9). BN, however, misconstrues § 1498.

⁴ BN suggests that Acambis’ motion to amend is some sort of “ploy” to force BN to file a lawsuit against the U.S. Government during a bidding process (D.I. 42 at 7). The timing, however, is based on the scheduling order in this case, which BN filed. Moreover, it was BN (not Acambis) that filed this action and the parallel ITC action just weeks before bids on RFP-3 were due (despite knowing the underlying factual basis for its claims for years).

Section 1498 is an affirmative defense -- not a jurisdictional bar -- and does not deprive a district court of jurisdiction. *See Toxgon Corp. v. BNFL, Inc.*, 312 F.3d 1379, 1381-82 (Fed. Cir. 2002) (“[S]ection 1498(a) is an affirmative defense rather than a jurisdictional bar. . . . [S]ection 1498(a) does not deprive a district court of jurisdiction.”); *Crater Corp. v. Lucent Technologies, Inc.*, 255 F.3d 1361, 1364 (Fed. Cir. 2001) (“[D]ismissal of a lawsuit against a private party pursuant to § 1498(a) is a dismissal because of the successful assertion of an affirmative defense rather than a dismissal because of the district court’s lack of subject matter jurisdiction over the patent infringement claim.”).

Indeed, courts have indicated that § 1498(a) affects only actions brought by a patentee, and does not affect actions brought by an alleged infringer, including declaratory judgment actions. *See Robishaw Eng’g, Inc. v. United States*, 891 F. Supp. 1134, 1144 n.21 (E.D. Va. 1995) (Section 1498(a) “would not bar a government contractor’s action for a declaratory judgment that it is not infringing patents in its government contract work.”); *Bath Iron Works Corp. v. Parmatic Filter Corp.*, 736 F. Supp. 1175, 1177 n.3 (D. Me. 1990) (“28 U.S.C. § 1498 . . . does not apply to actions brought by the alleged infringer of the patent.”).

Moreover, the Court of Federal Claims does not have jurisdiction to entertain declaratory judgments, *see Tchakarski v. United States*, 69 Fed. Cl. 218, 221 (Ct. Fed. Cl. 2005), and the ITC’s upcoming rulings on BN’s patents will not be given *res judicata* effect, *see Biotechnology General Corp. v. Genentech, Inc.*, 886 F. Supp. 377, 384 (S.D.N.Y. 1995) (“While the determinations of the ITC are given preclusive effect in cases not involving patent validity or invalidity, they have no such effect in patent cases.”). Thus, this Court is the only forum in which Acambis can seek a declaratory judgment to remove the threat of litigation and the cloud of BN’s assertions that Acambis’ MVA3000 product infringes BN’s patents.

**B. Acambis' Antitrust Counterclaims Properly Allege
"Antitrust Injury" And A "Dangerous Probability Of
Success"**

BN also argues that Acambis' antitrust counterclaims are futile because Acambis "cannot allege antitrust injury" (D.I. 42 at 3). BN is incorrect.

Acambis' antitrust counterclaims are based on BN's illegal efforts to monopolize the market for MVA-based smallpox vaccines and to prevent Acambis, a direct competitor of BN's and the only other recipient of U.S. Government contracts for MVA-based smallpox vaccines, from selling its MVA-based smallpox vaccine to the U.S. Government (D.I. 35, Ex. A, ¶¶ 3, 13-20). As set forth in the proposed counterclaims, BN has sought to effectuate its illegal scheme through baseless litigation against Acambis in the ITC and in this Court based on fraudulently procured and clearly invalid patents and other unsupported theories (*id.*, ¶¶ 41-49). Through that litigation and other illegal conduct, BN has sought to interfere with Acambis' ability to bid on, procure, and fulfill contracts offered by the U.S. Government, artificially decreased the value of Acambis stock, damaged Acambis' reputation and good will, and cost Acambis millions of dollars in litigation fees and costs to defend its right to compete in the market (*id.*, ¶¶ 67, 73).

Indeed, the litigation fees and costs alone are sufficient antitrust injury to support Acambis' antitrust counterclaims. *See, e.g., Rickards v. Canine Eye Registration Found., Inc.*, 783 F.2d 1329, 1334-35 (9th Cir. 1986) ("[T]he costs incurred in the defense of a suit filed in violation of the antitrust laws constitute antitrust injury . . ."); *Novo Nordisk of North America, Inc. v. Genentech, Inc.*, 885 F. Supp. 522, 525 (S.D.N.Y. 1995) ("[T]he costs incurred in connection with defending a litigation in which a patentee attempts to enforce patents that are invalid and unenforceable . . . is a well recognized type of antitrust injury . . .").

BN also argues that Acambis' antitrust counterclaims are futile because "Acambis does not allege that Bavarian Nordic has a dangerous probability of success in monopolizing a relevant antitrust market" (D.I. 42 at 4). Acambis has asserted, however, both monopolization and attempted monopolization claims (D.I. 35, Ex. A, ¶ 64), and "dangerous probability of success" is not a required element of a monopolization claim. *See, e.g., Volvo North America Corp. v. Men's Int'l Professional Tennis Council*, 857 F.2d 55, 73 (2d Cir. 1988). Moreover, Acambis' allegation that BN, by dint of its fraudulently obtained patents, has already succeeded in monopolizing the relevant market satisfies its requirement to allege a "dangerous probability of success." *See id.* at 74 ("[S]ince the complaint alleges both exclusionary conduct and the existence of monopoly power, the third element, a dangerous probability of success, may be inferred."); *Energex Lighting Indus., Inc. v. North American Philips Lighting Corp.*, 1990 WL 83528 (S.D.N.Y. 1990), at *4 ("If a genuine issue exists as to whether defendant succeeded in monopolizing the relevant market, it follows that there is at least a genuine issue as to whether plaintiff can prove a dangerous probability of success in monopolizing the market.").

In any event, Acambis does allege that BN claims that its patents give it the market power to prohibit *all others* from participating in the MVA-based smallpox vaccine market:

Upon information and belief, BN has asserted that it is the only company with freedom to operate to meet the terms of the U.S. Government's RFPs for MVA-based smallpox vaccines. For instance, on July 19, 2004, BN issued a public announcement to the Copenhagen Stock Exchange stating that, with the issuance of the '893 patent, "Bavarian Nordic are unique in their ability to affirmatively demonstrate their 'freedom to operate'" to meet RFP-2. In that same announcement, BN's President and CEO, Peter Wulff, stated that "with the issuance of this broad patent to the MVA-BN® virus and its like acting derivatives, it will be difficult for others to develop and produce a safe and effective MVA-based vaccine without a license under this patent." BN has further

asserted that MVA3000 infringes the '893 and '752 patents because it meets the requirements set forth in the U.S. Government RFPs.

(D.I. 35, Ex. A, ¶ 62; emphasis added).

Moreover, this is not the appropriate time, in addressing a motion to amend, to decide whether Acambis will be able ultimately to produce sufficient evidence to demonstrate BN's claimed "market power" and its "dangerous probability of success" in monopolizing the market. *See, e.g., Baltimore Luggage Co. v. Samsonite Corp.*, 977 F.2d 571, 1992 WL 296368, at *7 (4th Cir. 1992) (unpublished) ("At so early a stage in the case, the district court reasonably could have found that Baltimore's pleadings adequately stated a claim upon which relief could be granted subject to discovery to determine the extent of Samsonite's market power."); *Indiana Grocery Co. v. Super Valu Stores, Inc.*, 647 F. Supp. 254, 258 (S.D. Ind. 1986) ("Indiana Grocery's allegations . . . include considerable specific factual detail which the trier-of-fact must eventually consider and weigh in deciding whether section 2 has been violated.").

Finally, BN argues that Acambis' other counterclaims -- involving tortious interference, deceptive and unfair trade practices, and false representations -- are futile because Acambis has not suffered any injury (D.I. 42 at 3). In fact, Acambis has alleged that it has suffered injury, including damage to its reputation and an artificial decrease in its stock price (D.I. 35, Ex. A, ¶¶ 1, 67, 73). *See NuFarm v. RAM Research*, 1998 WL 668648, at *5 (Del. Ch. 1998) (denying motion to dismiss tortious interference claim where plaintiff alleged it "is suffering injury as a result of the competition, the delay in its repurchase of the Registrations and the harm to the Registrations from Nufarm Inc.'s alleged tortious interference."). This is more than BN has alleged by way of damages in support of its own claims. *See* D.I. 38, Ex. A at ¶¶ 52, 62, 68. Moreover, Acambis seeks an injunction on these claims, which does not require a calculation of damages.

CONCLUSION

For the foregoing reasons and those set forth in Acambis' Opening Brief, Acambis requests that its Motion For Leave To File Defendants' Amended Answer And Counterclaims be granted.

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CERTIFICATE OF SERVICE

I hereby certify that on June 14, 2006, I caused the foregoing to be electronically filed with the Clerk of the Court using CM/ECF which will send electronic notification of such filing to the following:

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Additionally, I hereby certify that true and correct copies of the foregoing were caused to be served on June 14, 2006 upon the following individuals in the manner indicated:

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